IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: *All cases identified on Exhibit A to Plaintiffs' Motion*	

REPLY MEMORANDUM IN FURTHER SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS OF DR. STANLEY ZASLAU

In further support of their Motion to exclude certain opinions and testimony of Defendants' Urology and Female Pelvic Medicine and Reconstructive Surgery expert, Stanley Zaslau, M.D., MBA, FACS ("Dr. Zaslau"), Plaintiffs state as follows.

ARGUMENT

I. Plaintiff's Motion to Exclude the Opinions and Testimony of Dr. Zaslau is not Moot

The Court has repeatedly noted that counsel should not expect the Court will align with its previous rulings "when faced with a different record," "especially when an expert has issued new reports and given additional deposition testimony."[1] Dr. Zaslau has issued an expert report on two new products, the Prolift and the Gynemesh PS, since this Court last considered the reliability of his proffered testimony, and has been deposed for an additional four hours

[1] *See, e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4608165, at *2 (S.D.W. Va. Sept. 2, 2016) citing, inter alia, *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993); *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001)); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2017 WL 1268790 (S.D.W. Va. Mar. 29, 2017) (Wave 2).

regarding the opinions he intends to offer.[2] Defendants point out that Dr. Zaslau was only disclosed to offer general causation opinions in one case in Wave 4, *Sandy Strunk, et. al*., Case No. 2:12-cv-04933. However, The *Strunk* case has not been dismissed, and Defendants have not withdrawn Dr. Zaslau as a general expert on Prolift or Gynemesh PS. Moreover, Dr. Zaslau has been offered as a general expert on the TVT and TVT-O in multiple cases in waves 1-3, and we are now faced with a different factual record going forward regarding the opinions he intends to offer about the pelvic mesh products. Thus, Plaintiff's motion challenging the opinions and testimony of Dr. Zaslau is not moot, and is ripe for consideration at this time.

II. Dr. Zaslau failed to apply any objective, reliable standard in offering his warning opinions, in violation of *Daubert*, and his opinion as the knowledge of other individuals is unreliable speculation.

Plaintiffs do not challenge Dr. Zaslau's credentials. Rather, Plaintiffs' argument is that Dr. Zaslau opinions are entirely subjective, without reference to any objective source or standard. The opposition brief fails to identify any standard or methodology applied by Dr. Zaslau, or any standard by which Dr. Zaslau's opinions on warnings can be objectively evaluated. That gap is fatal to Dr. Zaslau's warning opinions. In *Sanchez v. Boston Scientific Corp.*, 2014 WL 4851989 (S.D.W. Va. Sept. 29, 2014), this Court precluded an expert's warning opinions because the expert applied no standard at all to support his opinions, concluding: "Dr. Slack's subjective and conclusory approach is evidence that his opinion is based on mere speculation and personal belief." *Id.* at *32. The same applies to Dr. Zaslau, who has conducted no scientifically reliable inquiry into what physicians actually knew about the risk of the pelvic mesh devices.

Defendants have conceded that "to the extent that Plaintiffs' motion is directed at legal or regulatory opinions concerning the adequacy of the IFU, Dr. Zaslau will not offer such opinions at trial." (Def. Mem. in Opp. at 2-3). The Defendants' position is that Dr. Zaslau should be

[2] Mot. Ex. C & Ex. D.

permitted to testify concerning the knowledge of the medical community concerning the risks of the pelvic mesh devices. (*Id*. at 3). But Defendants' do not concede that Dr. Zaslau will not offer **any** opinions regarding the adequacy of the pelvic mesh IFUs. Thus, they clearly hope to have Dr. Zaslau testify that the risks associated with the devices were well known, and thus the IFU were adequate—despite the lack of foundation for any such opinion. This transparent effort to justify the expert's deficient methodology should not be allowed, as it asks the Court to allow Dr. Zaslau to offer opinions regarding the adequacy of the pelvic mesh IFUs without applying any objective standard or foundation. The sole "foundation" is the witness's speculative personal beliefs about what **he** thinks other doctors already know. Dr. Zaslau has performed no reliable or verifiable study of what surgeons knew about any issue. Dr. Zaslau admitted he lacked any foundation to opine as to what surgeons generally knew about the risks of pelvic surgery with mesh:

> Q. Have you ever done any kind of survey or used any kind of formal methodology to determine what physicians did or did not know with regard to the risks of the Prolift?
>
> A. You know, physicians have a wide variety of different things to learn about procedure from --
>
> [by defense counsel] first can you answer his question
>
> A. No, I have not done any survey myself
>
> **********
>
> Q. So have you done any kind of formal analysis to determine, for example, what percentage of Prolift users knew or did not know that pain was a potential risk from the Prolift IFU, or chronic pain?
>
> A. **No, I have not surveyed anyone or any – any group as to what their knowledge of the present IFU was.** But I know that anyone who reads a core textbook in urology or gynecology, even written back as far as 1998,

> knows that pelvic mesh can be associated with all the complications you are talking about, including pain.[3]

Thus, the only reliable testimony Dr. Zaslau as offered is what the contents of a 1998 textbook says about the risks of pelvic floor surgery, a textbook that was written at a time when the Prolift was not in existence yet.[4] Where Dr. Zaslau's testimony becomes unreliable is when he makes the leap to assume that all physicians have read said textbooks or literature as he has, and have fully understood and retained the contents, without any reliable basis or methodology in arriving at these conclusions. For the opinion that the risks were well known to physicians, we simply have Dr. Zaslau's say so, which is insufficient under *Daubert*. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999) (stating that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert").

This Court should not allow Dr. Zaslau's subjective, unsupported opinions regarding the knowledge of the medical community concerning the risks of the pelvic mesh devices. Such opinions should be precluded under Daubert and also Rule 403. The natural conclusion the jury would draw from this testimony is that the warning was adequate, despite the expert applying no objective standard to arrive at that conclusion. Defendants appear to concede that Dr. Zaslau is unable to opine about warnings in relation to legal or regulatory standards. Yet, they do not concede that he will not opine about warnings generally. (Mem. in Opp. at 2-3). Such testimony has little probative value and would lead to undue prejudice and confusion of the issues, under the balancing test provided by Rule 403. For all of these reasons, the Court should prohibit Dr. Zaslau from opining as to what other physicians knew about the risks associated with Ethicon's products.

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[3] Mot. Ex. D, 152:19-153:4; 153:12-23 (emphasis added)

[4] The Prolift was Introduced in 2004

III. Dr. Zaslau is not qualified to give opinions on the design of the mesh products, he has relied on no objective standard in reaching his conclusions regarding the safety and efficacy of the mesh products, and his opinions should be excluded.

Dr. Zaslau is admittedly not an expert in design, and Defendants appear to concede that he is not offering any opinions on design, but rather is offering opinions regarding safety and efficacy. (Mem. in Opp. at 4-5). By opining that the mesh products are safe and effective, Dr. Zaslau is, in effect, stating that the design is safe and effective. Dr. Zaslau's use of mesh products, and his qualifications as a board-certified urogynecologist do not, by themselves, qualify him to opine regarding the safety and efficacy of a medical device. Defendants claim that the foundation of Dr. Zaslau's opinions (which they characterize as safety and efficacy opinions) is his "knowledge, training, education, experience, and literature review." (Mem. in Opp. at 5). A review of the literature does not provide sufficient basis for Dr. Zaslau to offer a reliable design opinion unless he can identify an appropriate standard that she applied. *See Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015) (finding that Dr. Schull had not reliably applied the principles learned through his experience and the literature to the facts of this case because he had not seen any standard operating procedures or design protocols for the development of the medical device in question).

Here, in addition to admitting not being an expert in design, Dr. Zaslau has applied no objective standard for his opinions that the Prolift devices are safe and effective:

> Q. So how high would the erosion rate [of the Prolift] need to be before you would say that's too high of an erosion rate, it's not safe and effective?
>
> A. **I can't give you a number.** Because it's not based on a number. The number is factual. It's going to be based on clinical experience. It's going to be based on multiple papers suggesting the same thing, that there is a problem, It's going to be based on presentations at national meetings. It's going to be based on book chapters describing this, the latest edition of

> Campbell's Urology. I think it's going to take a body of literature, significant, compelling literature.
>
> ******
>
> Q. So are there any devices, medical devices out there that you believe are not safe and effective for their intended use?
>
> A. Not that I work with in Urology.
>
> Q. What is an example of a medical device that you think is not safe and effective for its intended use?
>
> A. I can't think of any.[5]

According to Dr. Zaslau's "standards," safety and efficacy are purely subjective. Dr. Zaslau admitted that he could potentially find that a pelvic mesh device which eroded in 100 percent of cases might still be safe and effective.[6] He has admitted he cannot state an objective standard for safety and efficacy.[7] As such, he should be precluded from giving any opinions related to the adequacy of the design, safety, and efficacy of the mesh products.

IV. Dr. Zaslau's particle loss and fraying opinions are still not reliable.

Plaintiffs argued that there is no scientific reliability to Dr. Zaslau's claim that he has not personally observed mesh particle loss or fraying. (Pl. Memo in Support at 12). In response, Ethicon asserts:

> Dr. Zaslau's statement *does not suggest* that the absence of degraded particles in meshes Dr. Zaslau has seen is evidence that such particles *are absent in all cases*. Instead, his statement is just part of his basis for his opinion that there is no clinically significant difference between machine-cut and laser-cut mesh.

(Mem. in Opp. at 6). First, if Dr. Zaslau cannot opine on the occurrence of particle loss and fraying of mesh generally, then his untested, unrecorded, and unverified "observations" from his

[5] Mot. Ex. D, 123: 6-18; 125: 15-22 (emphasis added)
[6] *Id*. at 123:19-125:17;
[7] *Id*. at 123:6-9; see also 128:17-22

own surgeries are useless to the jury. Moreover, if Dr. Zaslau has not observed these phenomena, he has no basis to opine that if they do occur, they are not clinically significant. Indeed, if Dr. Zaslau has no actual knowledge of the degradation or its effects in those cases, how can he claim that it is not clinically significant? He cannot. In other words, Dr. Zaslau's testimony is even more unreliable and irrelevant than the "I have not seen it, so it does not occur" testimony that this Court has previously excluded.[8] Here, Dr. Zaslau essentially wants to tell the jury: "I have not seen it. I am not actually sure whether or not it occurs. But if it does occur, I *suspect* that it is not serious."

Finally, Ethicon simply ignores Plaintiffs' argument that Dr. Zaslau admitted to not even knowing that there was a difference between laser-cut and mechanical-cut mesh prior to this litigation. Simply put, Dr. Zaslau is not capable of providing useful or reliable expert testimony on this issue.

V. Ethicon's response does not support or justify Dr. Zaslau's "sheath opinion."

Ethicon argues that Dr. Zaslau's opinion that mechanical-cut mesh will not rope or curl when properly implanted using the accompanying plastic sheath is based "on reliable *ex vivo* experiments and *in vivo* observations." (Mem. in Opp. at 7-8).

First, if Ethicon claims that Dr. Zaslau has conducted "*ex vivo* experiments" on the mesh, that "testing" should be excluded as unreliable and unscientific. Dr. Zaslau has not provided any information or documentation relating to these "experiments"—*e.g.* no written protocol; no testing parameters; no controls; no information on sample size; no indication of the specific mesh product or pull-force used, or conditions present during testing; no record of the data or results; no published findings; and no discussion of the scientific standards followed. Dr. Zaslau simply claims to have, at some point in the past, "pull[ed] on" some mesh, with and without a sheath.

[8] *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 583-85 (S.D. W. Va. 2014)).

(Mem. in Opp. at 8). To call these "experiments" is an affront to the scientific method. And, these so-called experiments cannot be verified, tested, or repeated by anyone, contrary to Defendants' assertions. (*See* Mem. in Opp. at 8). As such, they cannot stand as a basis for reliable expert testimony. Indeed, this Court has previously excluded much more detailed, verifiable, and scientific testing than this. *E.g. Mathison v. Boston Sci. Corp.*, NO. 2:13-cv-05851, 2015 U.S. Dist. LEXIS 59047 at *68-69 (S.D. W. Va. May 6, 2015) (excluding testing of Dr. Dunn).

Moreover, Ethicon makes no arguments in support of its claim that Dr. Zaslau relied on "*in vivo* observations." As Plaintiffs point out in their memorandum, Dr. Zaslau admits that these opinions are contradicted by the scientific literature, and he cannot provide any support for them other than what he claims to have "seen." (Pl. Mem. in Support at 13). Plaintiffs should not be required to just "take [his] word for it." (Zaslau Dep., March 17, 2016, Dkt. No. 3669-11, at 102:1-103:5).

VI. Dr. Zaslau should be precluded from testifying that polypropylene does not degrade *in vivo*.

Ethicon claims that Plaintiffs ignore the fact that Dr. Zaslau's opinions are based on the peer-reviewed literature that post-dates internal Ethicon internal documents. (Mem. in Opp. at 9). But Ethicon does not follow up that assertion by providing an explanation or examples of how Dr. Zaslau ruled out these internal documents as unreliable, or otherwise explain his methodology in arriving at his conclusions. Instead, Ethicon merely restates Dr. Zaslau's opinion that if degradation does occur, it is not clinically significant. (Mem. in Opp. at 9-10). There was no confusion about what Dr. Zaslau seeks to tell the jury.

There also is nothing "out-of-context" about the testimony that Plaintiffs quoted in their memorandum. Dr. Zaslau admitted that he did not, and would not, consider the scientific

literature or other evidence relating to degradation. (Dkt. No. 3669-11 at 124:16-125:3; *see also* 126:15-24; 127:21-24; 160:20-23). Instead, Dr. Zaslau chose to ignore that relevant evidence.[9] For this reason alone, Dr. Zaslau should not be permitted to opine that "there are no reliable scientific studies evaluating TVT or TVT-O that have demonstrated any clinical significance to alleged…degradation." (Mem. in Opp. at 9).

Ethicon's reliance on this Court's ruling with regard to Dr. Pramudji in *Huskey* is not conclusive on this issue. First, to the extent there is a conflict between that ruling and the Court's ruling in *Tyree*—where the Court rightly opined that the "absence of evidence is not evidence of absence"—the Court's more recent ruling in *Tyree* should apply. *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 583-85 (S.D. W. Va. 2014)). Moreover, the Court's opinion in *Huskey* only permitted Dr. Pramudji to testify "whether she has observed mesh degradation in her clinical practice." *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 726-727 (S.D. W. Va. 2014). That is a completely different—and much more benign—opinion than Dr. Zaslau's claims that "degradation is not clinically significant." (*See* Def. Mem. in Opp. at 9-10). Regardless of what he claims to have observed, he has absolutely no support for those opinions.

VII. Dr. Zaslau's opinion that the TVT is not associated with chronic or long term pain is completely unsupported, and therefore, unreliable.

As Plaintiffs pointed out in their memorandum, Dr. Zaslau could not provide a single piece of support for his proffered testimony that "[v]ery few people who have had a carefully-implanted device will have *long-term* pain." (Dkt. No. 3669-11 at 72:10-12; 72:22-73:20; *see also* 74:5-75:19). Ethicon claims that Plaintiff is "wrong"—citing to the fact that Dr. Zaslau made reference to the Tommaselli meta-analysis. (Mem. in Opp. at 12, *citing* Dkt. No. 3669-11

[9] *See Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 U.S. Dist. LEXIS 137189 at *70 (S.D. W. Va. Sept. 29, 2014).

at 74:5-22). But Dr. Zaslau himself acknowledged that the article does not qualify as a "long-term" study.[10] This is not simply a situation where Dr. Zaslau had an "inability to recall" something at the time of his deposition, as Ethicon seeks to portray it. Dr. Zaslau was given, and took, the opportunity to review his reliance materials. After which, he admitted that he "can't think of or find one that specifically refers to that for the long-term." (Dkt. No. 3669-11 at 72:22-73:20).

VIII. Dr. Zaslau should be precluded from offering precise statistics regarding his own personal experiences with the mesh.

Ethicon cites *Trevino v. Boston Sci. Corp,*[11] for the proposition that this court should allow Dr. Zaslau to offer opinions and testimony regarding his general personal experiences with mesh products. (Mem. in Opp. at 15-16). However, the situation with Dr. Zaslau is wholly distinguishable from *Trevino*. Here, Dr. Zaslau wishes to offer an opinion that none of his Prolift patients required additional repairs, and that they were all satisfied.[12] Essentially, this amounts to testifying to a 100% patient satisfaction rate, a 0% dissatisfaction rate, a 100% success rate, and a 0% re-operation rate, with no foundation or reliable methodology in arriving at these precise statistics. This is exactly the kind of testimony this court has excluded in the past. *See In re Ethicon*, 2016 WL 4542054 (S.D. W. Va. 2016). Therefore, this Court should exclude Dr. Zaslau from testifying as to his personal experiences with the mesh products in this case.

CONCLUSION

For the reasons stated above and in Plaintiffs' initial brief, Plaintiffs respectfully request that the Court grant their Motion to Exclude Certain Opinions of Stanley

[10] Plaintiffs are not saying that all short-term or middle-term studies are irrelevant. The point is that a long-term study would clearly be needed to assess long-term pain.
[11] Def. Mem. at 15-16
[12] Mot. Ex. D at 115:23-116:7

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 4, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

s/ Thomas P. Cartmell